NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES, LTD. and TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC. Defendants.	Civ. No. 07-2894 (GEB) (JJH) **MARKMAN OPINION**

BROWN, Chief Judge

This matter comes before the Court upon the parties' request for claim construction in this patent infringement action. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 2201, 2202, 1331 and 1338(a). On June 19, 2008, the Court held a claim construction hearing ("Markman Hearing"), during which the Court reserved judgment as to the construction of one disputed term. The Court will now addresses this remaining issue.

BACKGROUND

This patent infringement dispute concerns patents owned by Teva relating to processes for the preparation of carvedilol, the active pharmaceutical ingredient in COREG®, a product sold by GlaxoSmithKline for the treatment of congestive heart failure. (Compl. ¶ 8, 18.)

On June 21, 2007, plaintiffs Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva") brought suit against Dr. Reddy's Laboratories,

Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") for infringement of certain patents held by Teva. On January 31, 2008, the parties filed Opening Claim Construction Briefs with the Court. Opposition Briefs were filed on February 29, 2008. The parties also filed a Joint Claim Construction Chart identifying the disputed claim terms, as well as stipulated constructions, on March 17, 2008. Pursuant to the Court's June 2, 2008 order, DRL filed a letter on June 6, 2008 in which it clarified its position with respect to the claim term "dry." On June 10, 2008, Teva responded by letter.

The parties agree that claim construction is needed for only one patent: U.S. Patent No. 6,710,184 ("the '184 Patent"). The '184 Patent has four claims and is entitled "Crystalline Solids of Carvedilol and Processes for Their Preparation." Claim 1 is the sole independent claim in the '184 Patent; the remaining dependent claims specify additional limitations or conditions on the process identified in claim 1. (Teva Br. at 4; DRL Br. at 4.) Claim 1 reads as follows:

> A process for preparing a crystalline solid of carvedilol Form II comprising the steps of:
>
> heating crystalline carvedilol or a solvate thereof characterized by data selected from the group consisting of PXRD pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a DSC thermogram with endothermic peaks at about 74°C and 112°C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1} until the crystalline carvedilol is dry, mixing carvedilol Form II with the dry crystalline carvedilol, and storing the mixture for a holding time sufficient to transform the dry crystalline carvedilol into Form II.

('184 Patent Col.8, lines 35-49.)

At the start of the Markman Hearing, the parties alleged that there were five disputed terms in claim 1 of the '184 Patent: (1) "carvedilol Form II"; (2) "solvate"; (3) "crystalline carvedilol or a solvate thereof characterized by data selected from the group consisting of PXRD

pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a DSC thermogram with endothermic peaks at about 74°C and 112°C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}"; (4) "dry"; and (5) "a holding time sufficient to transform the dry crystalline carvedilol into Form II."

During the Markman Hearing the parties came to an agreement as to three of these terms: (1) "carvedilol Form II"; (2) "dry"; and (3) "a holding time sufficient to transform the dry crystalline carvedilol into Form II." Therefore, the Court need not construe those terms.

For reasons explained on the record at the Markman Hearing, the Court ruled that the term "solvate" means "an aggregate that consists of one or more solute ions or molecules with one or more solvent molecules."

The Court reserved judgment as to the construction of the term "crystalline carvedilol or a solvate thereof characterized by data selected from the group consisting of PXRD pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a DSC thermogram with endothermic peaks at about 74°C and 112°C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}." The Court will now address this issue.

DISCUSSION

I. Law of Claim Construction

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. Id. at 979. The Federal Circuit clarified the proper methodology

for claim construction in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005). The court stated that the claims of a patent serve as the proper starting point, noting the "bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Id. at 1312 (quotations omitted) (citing Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The court articulated that words should generally be given their ordinary and customary meaning – particularly from the vantage point of a person of ordinary skill in the art. Phillips, 415 F.3d at 1313. This provides an objective baseline from which claim construction should begin. Id.

Significantly, the Federal Circuit further noted that a "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. In attempting to discern the meaning of claim terms, the court identified various sources from which the proper meaning may be determined. The claim in which the term appears and other claims of a patent, including both asserted and unasserted claims, can serve as "valuable sources of enlightenment as to the meaning of the claim term." Id. at 1314.

The court also emphasized the primacy of the specification in a claim construction analysis, noting that it is usually dispositive and "the single best guide to the meaning of a disputed term." Id. at 1315. The specification may reveal whether the patentee acted as his own lexicographer by importing a special definition to the claim term – in which case, the patentee's lexicography governs. Id. at 1316. Moreover, the specification can further reveal any intentional disavowal or disclaimer of claim scope. In such instances, "the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as

dispositive." Id.

The prosecution history should also be taken into consideration if in evidence. Consisting of the complete record of the Patent and Trademark Office ("PTO") proceedings, "the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. Unlike the specification, however, which represents the final product of ongoing negotiations between the PTO and the patentee, the prosecution history may lack clarity and thus, serves as a less helpful tool in claim construction. Id. Nonetheless, this part of the intrinsic evidence "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id.

The Federal Circuit cautioned against the use of extrinsic evidence during claim construction since this type of evidence suffers from certain inherent flaws which affect its reliability in a clam construction analysis. This class of evidence includes "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. at 1317 (quoting Markman, 52 F.3d at 980). Although extrinsic evidence may be useful, "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Id. at 1319. A court nonetheless is permitted to admit and use extrinsic evidence in its sound discretion, so long as the court remains mindful of the inherent flaws in this type of evidence and considers it accordingly. Id.

Phillips also clarified the role of dictionaries in claim construction. Placing undue reliance on dictionaries would improperly focus "the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." Id. at 1321. The

"ordinary meaning" of the claim term is properly viewed as the "meaning to the ordinary artisan after reading the entire patent." Id. Moreover, dictionaries are naturally suspect as they "provide an expansive array of definitions" and often collect all uses of a word "from the common to the obscure." Id. This may result in extending "patent protection beyond what should properly be afforded by the inventor's patent." Id. at 1322. Despite such concerns, however, courts are not precluded from using dictionaries in the appropriate manner during claim construction analysis. Id.

Lastly, the Court must be mindful of the well-settled rule "that while proper claim construction requires an examination of the written description and relevant prosecution history to determine the meaning of claim limitations, additional limitations may not be read into the claims." Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 831 (Fed. Cir. 2003); see also In re Donaldson Co., 16 F.3d 1189, 1195 (Fed. Cir. 1994) (noting the "general claim construction principle that limitations found only in the specification of a patent or patent application should not be imported or read into a claim.").

II. Application to the Claim Term "crystalline carvedilol or a solvate thereof characterized by data selected from the group consisting of PXRD pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a DSC thermogram with endothermic peaks at about 74°C and 112°C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}"

A. Proposed Constructions

DRL proposes that the Court construe this term as "crystalline carvedilol solvate Form VI." In the joint claim construction chart, Teva states that it "disagrees that this phrase should be construed as a whole and has provided proposed constructions for the individual terms within."

However, in its Responsive Claim Construction Brief, Teva argues that the term should be construed as: "Crystalline carvedilol or a solvate thereof having at least one of the listed characteristics: A powder X-ray diffraction pattern with peaks at approximately 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a differential scanning calorimetic thermogram with endothermic peaks at approximately 74 °C and 112 °C.; or a FTIR spectrum with peaks at approximately 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}." (Teva Resp. Br. at 12.)

In the claim construction chart, Teva seeks to construe individually the following components of the disputed term: (1) "characterized by data selected from the group consisting of"; (2) "a PXRD pattern with peaks pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta"; (3) "a DSC thermogram with endothermic peaks at about 74°C and 112 °C"; and (4) "a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}." DRL opposes piecemeal construction, but nonetheless addresses each of the individual terms.

Teva proposes that the Court construe "characterized by data selected from the group consisting of" as "having at least one of the listed characteristics." DRL proposes the following construction: "characterized by at least one of the following sets of physical data."

Teva proposes that the Court construe "a PXRD pattern with peaks pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta" as "a powder X-ray diffraction pattern with peaks at approximately 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta." DRL disagrees that "PXRD" needs to be construed because a person of ordinary skill in the art would understand that "PXRD" in the claim refers to powder X-ray diffraction. In addition, DRL states that the

Court need not construe "about" because the claim itself specifies what is meant by this term. According to DRL, a person of ordinary skill in the art would recognize that "about" in the claim refers to the deviation from the claimed peaks that is permissible, which is explicitly stated in the claim to be "±0.2 degrees two-theta."

Teva proposes that the Court construe "a DSC thermogram with endothermic peaks at about 74°C and 112 °C." as "a differential scanning calorimetric thermogram with endothermic peaks at approximately 74°C and 112°C." DRL disagrees that "DSC" needs to be construed because a person of ordinary skill in the art would understand that "DSC" in the claim refers to differential scanning calorimetry. In addition, DRL states that the Court need not construe "about" in the claim because a person of ordinary skill in the art familiar with DSC data would understand what is meant when peaks are designated as falling "at about" certain temperatures, and how experimental conditions might affect a reported DSC measurement.

Teva proposes that the Court construe "a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}" as "a FTIR spectrum with peaks at approximately 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}." DRL disagrees that "FTIR" needs to be construed because a person of ordinary skill in the art would understand that "FTIR" in the claim refers to Fourier transform infrared spectroscopy. In addition, DRL states that the Court need not construe "about" in the claim language because a person of ordinary skill in the art familiar with FTIR spectra would understand what is meant when peaks are designated as falling "at about" certain wavelengths, and "in particular what amount of deviation from a specified wavelength is permissible for a peak to still be considered to fall at that wavelength."

B. Arguments

1. DRL

In support of its proposed construction of the disputed term as a whole, DRL references the portion of the specification that states: "Carvedilol solvate Form VI is characterized by a PXRD pattern (FIG. 1) with peaks at about 6.5, 7.3, 16.0, and 30.5 +- 0.2 degrees two-theta." ('184 Patent, col.3, lines 35-37.) DRL also cites the portion of the specification that states that "Carvedilol solvate Form VI produces a FTIR spectrum (FIG. 2 with characteristic absorption bands at about, 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}" and that Carvedilol solvate Form VI "produces a DSC thermogram (FIG. 3) showing two endothermic peaks: the main endothermic peak was observed at about 74°C and a minor endotherm (dH=0.71J/g) was observed at 112°C." (Id. at col. 3, lines 40-49.)

DRL also references the prosecution history. The examiner of the '184 patent stated: "Applicant's claims relate to a process of preparing a solid crystal of form II carvediol [sic] by employing carvediol [sic] of form VI. The closest prior art of record . . . teach process of making crystals of form II, however, this reference does not teach or fairly suggest the preparation of form II by employing the carvediol [sic] of form VI. Therefore, claims 24-27, renumbered 1-4 are allowed." (Imbacuan Decl. Ex. 8 ("Notice Allowability") at 4.) DRL argues that because the inventors did not dispute this characterization of the claims, they cannot now argue that the claim term means something other than crystalline carvedilol solvate Form VI.

b. Teva

Teva argues that DRL's proposed construction ignores the "Markush group" claim language "characterized by data selected from the group consisting of." Teva contends that this

language is a way to list "specified alternative of a group in a patent claim." According to Teva, if any one of the listed PXRD pattern, DSC thermogram, or FTIR spectrum data is satisfied, the claim limitation is met. Teva concludes that "[g]iven its language, this claim term may be satisfied by a compound that does not meet the entire set of data corresponding to carvedilol solvate Form VI."

In further support of its construction, Teva references the specification, which identifies the three sets of data in the disputed term as being associated with carvedilol solvate Form VI and states that "[t]he present invention provides a process for preparing a crystalline solid of carvedilol Form II, including the steps of heating crystalline carvedilol having at least one characteristic of Form VI." ('184 Patent col.3, lines 14-17; col. 4, lines 20-23.)

Teva also argues that DRL improperly "attempts to limit this claim term to the solvate form" by ignoring the claim language "or a solvate thereof." Additionally, Teva notes that the specification defines "PXRD" as "powder x-ray diffraction' (Id. col.1, line 56-57), and "DSC" as "differential scanning calorimetric." (Id. col. 2, line 26-27.)

Finally, Teva argues that the Federal Circuit has previously rejected the exact argument put forth by DRL regarding the preclusive effect of Teva's silence in the face of the patent examiner's statements. Teva also notes that "DRL's prosecution history argument is inconsistent with its proposed construction, as the examiner's statement referred to carvedilol Form VI, not carvedilol solvate Form VI." (Teva Response Br. at 12 (emphasis in original).)

C. The Court's Construction

The Court will construe "crystalline carvedilol or a solvate thereof characterized by data selected from the group consisting of PXRD pattern with peaks at about 6.5, 7.3, 16.0, and

30.5±0.2 degrees two-theta; a DSC thermogram with endothermic peaks at about 74 °C and 112 °C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm $^{-1}$" as "crystalline carvedilol or a solvate thereof having at least one of the following characteristics of Form VI: A powder X-ray diffraction pattern with peaks at approximately 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a differential scanning calorimetric thermogram with endothermic peaks at approximately 74 °C and 112 °C.; or a FTIR spectrum with peaks at approximately 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm $^{-1}$."

First, the three groups of data listed in the disputed term constitutes a Markush group. Indeed, DRL conceded this point at the Markman Hearing. Under Federal Circuit law, the claim language "characterized by data selected from the group consisting of" indicates that the methods of analysis listed are alternatives. See Abbott Labs. v. Baxter Pharm. Prods., 334 F.3d 1274, 1280 (Fed. Cir. 2007) ("A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C."); see also MPEP § 2173.05(h) ("One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being 'selected from the group consisting of A, B and C.'") (citing Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925)). "It is well known that 'members of the Markush group are . . . alternatively usable for the purposes of the invention.'" Abbott Labs, 334 F.3 at 1280 (citing In re Driscoll, 562 F.2d 1245, 1249 (CCPA 1977)).

Second, at the Markman Hearing the parties agreed that the three sets of data in the disputed term's Markush group (the PXRD data, the DSC data and the FTIR data) correspond to

Form VI. Indeed, the specification directly supports this:

> In one aspect, the present invention provides a crystalline solid of carvedilol or a solvate thereof characterized by data selected from the group consisting of a PXRD pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta, a PXRD pattern with peaks at about 5.8, 10.7, 11.1, 11.5, 13.1, 13.7, 16.8, 17.7, 18.5, and 23.0±0.2 degrees two-theta, a DSC thermogram with endothermic peaks at about 74 °C and 112 °C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}. Said solid crystalline form denotes Form VI.
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> In another aspect, the present invention provides a process for preparing a crystalline solid of carvedilol of a solvate therof having at least one characteristic of Form VI (such as the PXRD peaks and/or FTIR peak, and/or DSC peaks disclosed herein).

(Id. col. 2, line 60 - col 3, line 8.) The specification also states, in two different places, that "[t]he present invention provides a process for preparing a crystalline solid of carvedilol Form II, including the steps of heating carystalline carvdedilol having at least one characteristic of Form VI." ('184 Patent col.3, lines 14-17; col. 4, lines 20-23.) Additionally, the specification reads as follows:

> In one aspect, the present invention provides a novel crystalline solid of carvedilol or a solvate thereof, designated Form VI. Carvedilol solvate Form VI is characterized by a PXRD pattern (FIG. 1) with peaks at about 6.5, 7.3, 16.0, and 30.5 +- 0.2 degrees two-theta. Further PXRD peaks were observed at about 5.8 , 10.7, 11.1, 11.5, 13.1, 13.7, 16.8, 17.7, 18.5, and 23.0±0.2 degrees two-theta.
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> Carvedilol solvate Form VI produces a FTIR spectrum (FIG. 2 with characteristic absorption bands at about, 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}. Further FTIR peaks were observed at about 720, 110, 1286, 1454, 1589, 2911, and 2935 cm^{-1}.
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> Carvedilol solvate Form VI produces a DSC thermogram (FIG. 3) showing two endothermic peaks: the main endothermic peak was observed at about 74°C and a minor endotherm (dH=0.71J/g) was observed at 112°C.
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> Carvedilol solvate Form VI produces a Differential Thrmal Gravimetry (DTG) thermogram (FIG. 4) showing a weight loss step in the temperature range of 35-104 °C. of about 13%.

(Id. col. 3, lines 33-52.) Thus, the disputed term addresses crystalline carvedilol or a solvate

thereof having at least one of the three characteristics of Form VI identified as part of the Markush group in the disputed term.

The disputed term does not require every characteristic of Form VI to be present. For example, the Differential Thermal Gravimetry thermogram data disclosed in the specification as corresponding to Form VI is not listed in the disputed term. Similarly, certain additional PXRD peaks and FTIR peaks disclosed in the specification are not listed in the disputed term. Thus, the disputed term does not relate to any characteristic of Form VI, but only to those specifically identified in the disputed term.

The Court's construction is consistent with the PTO examiner's statement that the "[a]pplicant's claims relate to a process of preparing a solid crystal of form II carvediol [sic] by employing carvediol [sic] of form VI. The closest prior art of record . . . teach process of making crystals of form II, however, this reference does not teach or fairly suggest the preparation of form II by employing the carvediol [sic] of form VI. Therefore, claims 24-27, renumbered 1-4 are allowed." (Notice Allowability at 4.) Presumably, Carvedilol Form VI contains at least one of the Form VI characteristics disclosed in the disputed term.[1]

Additionally, contrary to DRL's proposal, the Court will not restrict the construction to the solvate form, because the disputed claim language includes "crystalline carvedilol or a

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[1]The examiner's unilateral statement is relevant to claim construction. In fact, the Federal Circuit stated as follows:

> Although unilateral statements by an examiner do not give rise to a clear disavowal of claim scope by an applicant, it does not necessarily follow that such statements are not pertinent to construing claim terms. Statements about a claim term made by an examiner during prosecution of an application may be evidence of how one of skill in the art understood the term at the time the application was filed.

Salazar v. Proctor & Gamble Co., 414 F.3d 1342,1347 (Fed. Cir. 2005).

solvate thereof."

DRL objects to Teva's proposed construction of the language "characterized by data selected from the group consisting of" as "having at least one of the listed characteristics." DRL prefers the construction "characterized by at least one of the following sets of physical data." The Court sees no meaningful difference between these two proposals. In light of the specification's repeated use of the language "having at least one characteristic of form VI" ('184 Patent col.3, lines 14-17; col. 4, lines 20-23), the Court will construe "characterized by data selected from the group consisting of" as "having at least one of the following characteristics."

Finally, DRL does not substantively disagree with the other proposed constructions by Teva. DRL merely states that the Court need not construe the terms "PXRD," "DSC" and "about" because a person of ordinary skill in the art would understand what these terms mean. The Court sees no reason to depart from the ordinary, agreed meaning of these terms. See, e.g., Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1369-1370 (Fed. Cir. 2005) (reversing the district court's construction of "about" and holding that such term should be given its ordinary meaning of "approximately").

CONCLUSION

For the reasons set forth above, the disputed claim terms have the following meanings:

1. The claim term "solvate", as found in Claim 1 of the '184 Patent means, "an aggregate that consists of "one or more" solute ions or molecules with one or more solvent molecules."
2. The claim term "Crystalline carvedilol or a solvate thereof characterized by data selected

from the group consisting of PXRD pattern with peaks at about 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a DSC thermogram with endothermic peaks at about 74 °C and 112 °C.; and a FTIR spectrum with peaks at about 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}", as found in Claim 1 of the '184 Patent means "crystalline carvedilol or a solvate thereof having at least one of the following characteristics of Form VI: A powder X-ray diffraction pattern with peaks at approximately 6.5, 7.3, 16.0, and 30.5±0.2 degrees two-theta; a differential scanning calorimetric thermogram with endothermic peaks at approximately 74 °C and 112 °C.; or a FTIR spectrum with peaks at approximately 613, 740, 994, 1125, 1228, 1257, 1441, 1508, 1737, 2840, 3281, 3389, and 3470 cm^{-1}."

Dated: June 23, 2008

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.